

REMARKS/ARGUMENTS

Claims 1-19 have been previously withdrawn. Claim 21 has been cancelled. Claim 20 has been amended to include limitations presented in the cancelled claim. Therefore, no new search needs to be performed. Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

35 U.S.C. §102 Rejections

Claims 20-22 and 25-27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bagaoisan et al (US Patent 6,152,909) (hereinafter, "the Bagaoisan patent"). This rejection is traversed.

The Applicant has thoroughly considered the Examiner's remarks concerning the patentability of claims 20-22 and 25-27 over the Bagaoisan Patent. The Applicant has also thoroughly read the Bagaoisan Patent. In order for the Bagaoisan Patent to anticipate the invention as claimed in independent claim 20, the Bagaoisan Patent must disclose, teach, or suggest each and every claimed element of the Applicants' invention, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Amended claim 20 claims a system for treating a vulnerable plaque associated with a blood vessel of a patient including a balloon that ruptures a fibrous cap of the vulnerable plaque and a capture device that captures at least one embolus within the blood vessel. The Bagaoisan Patent does not teach, disclose or suggest a system for treating a vulnerable plaque having each and everyone of the claimed elements.

The Bagaoisan Patent does not teach, disclose or suggest a balloon rupture device for rupturing a fibrous cap of the vulnerable plaque. At most, the Bagaoisan Patent teaches devices for excising an occlusion by cutting, shaving, scraping, pulverizing or ablating the plaque that is within the wall of the vessel (see Bagaoisan, col. 7 lines 53-57).

Furthermore, device 52 of the Bagaoisan Patent is an occlusion device, not a rupture

device. There is no teaching or suggestion in the Bagaoisan Patent to use this device 52 as anything other than an occlusion device. The Examiner's allegation that the device may be used as a rupture device is evidence that the Examiner is using impermissible hindsight in rejecting these claims. For at least these reasons, the Bagaoisan Patent does not anticipate claim 20 of the present application and the rejection of claim 20 must fall. Claims 22 and 25-27 depending from independent claim 20 are allowable for at least the same reasons stated above for claim 20. Claim 21 has been cancelled. The withdrawal of the rejection of claims 20-22 and 25-27 under §102(b) is requested.

35 U.S.C. §103 Rejections

Claims 23-24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bagaoisan et al. '909, in view of Campbell et al. (US Patent 6,245,026). This rejection is traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. See MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the prior art references when combined fail to teach or suggest all the claim limitations and fail to provide the motivation to combine the references as the Examiner suggests.

As discussed above in regards to amended claim 20, the Bagaoisan Patent fails to teach all of the claim limitations of the amended claim. Further, the Campbell Patent fails to cure these defects. For this reason alone, the Examiner has failed to establish a *prima facie* case of obviousness and the rejection must fall. Additionally, as stated above, the Examiner has failed to establish a *prima facie* case of obviousness because there is no motivation to combine the references.

The rationale to modify or combine the prior art may be expressly or impliedly contained in the prior art *or* it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. MPEP §2144, *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See also In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

The Examiner properly does not cite to any express or implied teachings in either the Bagaoisan Patent or the Campbell Patent, as none of the references, alone or in combination, provides any such teaching. Therefore, the Examiner must be attempting to rely on either knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. However, the Examiner makes no citation to any established scientific principles, or precedent established by prior case law, and therefore can only be relying on knowledge generally available to one of ordinary skill in the art.

However, the Examiner provides no evidence of the ordinary skill in the art. In a case such as this, where the Examiner is improperly attempting to combine disparate references, the Examiner's omission of any details regarding the level of skill of one in the art is telling. The mere fact that references *can* be combined is *not sufficient* to establish obviousness under 35 U.S.C. §103(a). *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990), MPEP §2143.01.

In rejecting claims 23 and 24 as obvious the Examiner states that the Bagaoisan Patent discloses "a system of treating vulnerable plaque that includes all the limitations as

recited in claim 20.” The Applicant traverses this allegation. The Bagaoisan Patent does not teach any system for treating a vulnerable plaque. The Bagaoisan Patent only teaches a system of treating plaques that occlude a vessel lumen by scraping, cutting, shaving, pulverizing or ablating the plaque from the wall of the vessel (see Bagaoisan col. 7 lines 53-57). Nowhere in the Bagaoisan Patent does it teach using these same devices to treat a vulnerable plaque. Those with ordinary skill in the art understand and readily recognize the difference between a vulnerable plaque and an occlusive plaque and therefore, understand the differences in the methods and devices for treating such plaques (see Application pg. 6 lines 4-12). The Examiner has not shown that it is well known in the art to treat a vulnerable plaque by rupturing the fibrous cap. Those with skill in the art know that treatments heretofore specifically attempt to prevent the rupture of the fibrous cap to avoid the release of the embolic material contained within the lipid pool of the vulnerable plaque (see Application pg. 3 lines 11-15). Further, the Examiner points to no reference that teaches such a treatment. For at least this additional reason, the rejection of claims 23 and 24 as obvious over the Bagaoisan Patent in view of the Campbell Patent fails. The Applicant requests the withdrawal of the rejection of claims 23 and 24 under § 103(a).

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Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1746.

Respectfully submitted,

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